February 22, 2006

Burton Garten Indiana State Department of Health

Dear Mr. Garten:

Pursuant to IC 4-22-2-28, the Indiana Economic Development Corporation ("IEDC") has reviewed the economic impact analysis associated with Rule 410 IAC 15-1.4-2.2 proposed by the Indiana State Department of Health (ISDH). The proposed rule requires hospitals to have a serious adverse event reporting system in place by January 1, 2006 and requires reports of serious adverse events to be submitted to the ISDH not later than fifteen (15) days after the serious adverse event occurs. Data submission will occur online in real time utilizing the existing ISDH electronic portal. Hospitals must review the serious adverse events through their quality assessment and improvement program. The ISDH is required to analyze and publish the data no less than annually.

The fiscal impact to hospitals associated with this rule consists of initial expenses to implement the program as well as recurring expenses for hospitals in which serious adverse events occur. The total estimated employee compensated time per hospital for initial start-up compliance during the first year is twenty (20) labor hours. The ISDH expects these activities to be coordinated and performed by middle managers. The estimated total start-up expense based on estimated labor rates is \$500 [20 hours x \$25/hour]. The aggregate impact for the 160 affected hospitals is \$80,000.

Hospitals in which serious adverse events occur would experience administrative costs associated with complying with the rule. The time required for gathering the information, determining whether reportable, and filing the report is likely no more than two (2) hours every fifteen (15) days. At that rate, the estimated compliance hours incurred by providers per year would be forty-eight (48) hours per year. For hospitals with few or no reportable errors, the cost is proportionately lower. Hospitals reporting a significant number of errors would incur costs proportionately higher. The estimated recurring annual expense is \$1,200 [48 hours x \$25/hour] per hospital.

Based on the above assumptions, the average first year expense is \$1,700 [\$500.00 start-up costs plus \$1,200 recurring expenses] per hospital. The average expense for subsequent years is \$1,200 per hospital. The cost to the provider industry after year one is approximately \$192,000 annually [160 hospitals x \$1,200].

The report does not identify what percentage, if any, of affected hospitals would be classified as small businesses. However, the costs associated with the rule are necessary based on Executive Order 05-10, which requires the ISDH to establish a medical errors reporting system. The IEDC does not object to the fiscal impact associated with the proposed rule. The requirements imposed under the proposed rule will support improvements to the level of healthcare provided in Indiana. Hospitals can

reduce the cost associated with compliance with this rule by taking steps to reduce the number of serious adverse events occurring in their facility

If you have any questions about the comments contained herein please contact me at 232-8962 or rasberry@iedc.in.gov.

Ryan Asberry Director – Research

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Indiana Economic Development Corporation